

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Third-Party Review Under FDAMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

oc01164

Medical Devices; Third-Party Review Under FDAMA (OMB Control No. 0910-0375)—

Extension

Section 210 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) established a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the third-party pilot program conducted previously by FDA, participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low to moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of May 29, 2001 (66 FR 29142), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| Item | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Requests for accreditation | 40 | 1 | 40 | 24 | 960 |
| 510k reviews conducted by accredited third parties | 35 | 4 | 140 | 40 | 5,600 |
| Total | | | | | 6,560 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| Item | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 510(k) reviews | 35 | 4 | 1,140 | 10 | 1,400 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens are explained as follows:

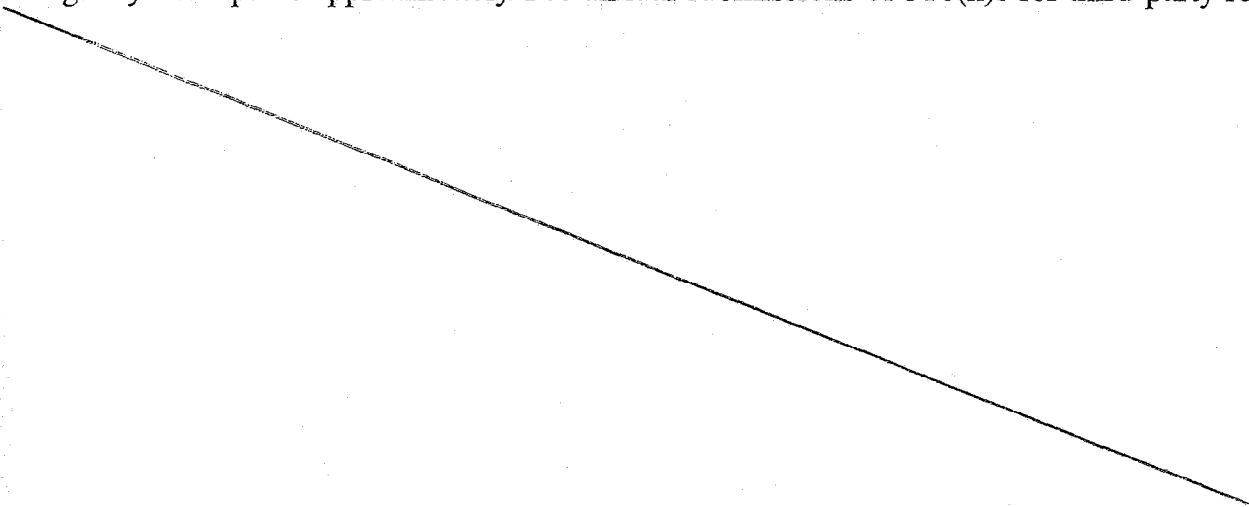
1. Reporting

a. *Requests for accreditation.* Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties.* In the 18 months under the third-party review pilot program, FDA received only 22 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 1998. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

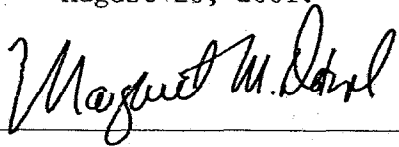
Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)s for third-party review.



The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) is derived from agency records and experience.

Dated: 8/20/01

August 20, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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